

Chapter 1 Introduction

1.1 Purpose and Scope

This manual, ***Risk Assessment Handbook: Volume II - Environmental Evaluation***, provides technical guidance to the U.S. Army Corps of Engineers (USACE) risk assessors and risk assessment support personnel for planning, evaluating, and conducting ecological risk assessments (ERAs) in a phased Hazardous, Toxic, and Radioactive Waste (HTRW) response action. The manual, a compendium to the ***Risk Assessment Handbook: Volume I - Human Health Evaluation*** (EM 200-1-4, USACE 1995a), encourages the use of “good science*” within the framework of existing U.S. Environmental Protection Agency (EPA) ERA guidelines. The purpose of this manual is to provide USACE HTRW program managers and technical proponents with recommended basic/minimum requirements for planning, evaluating, and conducting ERAs and to define the expected quality and goals of the overall program.

Risk characterization is a similar process for both human health and ecological risk assessments. The fundamental paradigm for human health risk characterization has four phases: (1) hazard identification, (2) dose-response assessment, (3) exposure assessment, and (4) risk characterization. Similarly, the fundamental framework for ecological risk characterization includes four analogous phases: (1) problem formulation, (2) ecological effects characterization, (3) exposure characterization, and (4) risk characterization.

This manual encourages the concurrent assessment of human and ecological risks so that data collection activities are coordinated and risk managers are provided risk characterization results in a timely manner. Risk characterization results for human and ecological receptors should be reasonable and communicated to the risk managers in a clear and unbiased manner to facilitate the making of balanced and informed risk management decisions.

1.1.1 Objectives

The overall objective of this manual is to allow the users to be familiar with the ERA process so that quality data will be collected and used in preparing a site-specific ERA. Specifically, the objectives are:

- To provide guidance for all ERAs completed under contract with USACE or those which USACE provides technical oversight (including active and formerly used defense sites [FUDS] and other Federal agencies/facility sites), in compliance with Federal environmental laws and regulations.
- To allow users to be familiar with the application of the data quality design process with respect to conducting ERAs, so that data collected will support ERA conclusions.
- To highlight those decision criteria specific to each phase of project execution that support risk management decision-making within the framework of USACE’s HTRW programmatic approach.
- To provide minimum requirements for evaluating contractor-prepared ERAs, ensuring that the assessment will adequately support site decisions of an HTRW response action.
- To acknowledge areas of uncertainties where “good science,” based on professional judgment and sound scientific principles, is used to determine the need for removal actions or interim measures, further investigation, further action, or no further action needed (site closeout).
- To refine understanding of EPA’s concepts and application of ERA guidelines for site assessment and remediation, especially to support the USACE HTRW program goals.

1.1.2 Scope

This guidance manual is not intended to be a “how to” manual which prescribes step-by-step procedures or instructions for preparing an ERA. Rather, the manual presents recommendations for scoping, managing, evaluating, and communicating to risk managers and other stakeholders the potential ecological risks posed by hazardous chemicals of ecological concern (COECs) at Resource Conservation and Recovery Act (RCRA) sites, Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) sites, and other sites managed under the HTRW program. This manual provides concepts for performing an ERA consistent with “good science” and accepted regulatory procedures. The following areas are not covered herein:

- Biological hazards - microbes (natural or genetically engineered) and other biological agents, including their use and impact to the indigenous species and environment.
- Radioactive hazards - radioactive wastes, radiation-generating devices, and radioactively contaminated materials.
- Study elements and regulatory requirements of a Natural Resource Damage Assessment (NRDA) -- (However, information presented in Chapter 2 of this manual could be helpful to HTRW sites mandated for NRDA actions.)

1.1.3 Intended Audience and Use

This manual is primarily for use by USACE personnel who are responsible for scoping, directing, and reviewing ERAs performed for HTRW response action sites. The guidelines provided herein are consistent with and should be considered in addition to existing EPA guidance contained in the Risk Assessment Guidance for Superfund. Volume II, Environmental Evaluation Manual (EPA 1989a), the Framework for Ecological Assessment (EPA 1992a), and the National Research Council's Issues in Risk Assessment (NRC 1994). The engineer manual entitled, Technical Project Planning - Guidance for HTRW Data Quality Design (USACE 1995b) should be reviewed, particularly for understanding the process described in Chapter 2 herein on how to determine data quality objectives (DQOs) to support an ERA.

The data collection, assessment, characterization of risk and uncertainty, and the risk management decision-making aspects presented in the following chapters are intended to satisfy RCRA and CERCLA regulatory requirements. The assessment of ecological risks under these two functionally equivalent programs is essentially the same. The concepts and assessment techniques presented below can be used to optimize data quality design across regulatory program requirements (if applicable) and justify or demonstrate that certain units or sites could be combined and assessed as a single entity according to the concept of establishing a corrective action management unit (CAMU) or temporary units (TU). If both regulatory programs are applicable at a site or unit, the ecological assessment components should be closely coordinated to avoid duplication of effort. Where possible, the technical and risk management approaches should be incorporated as specific language in agreements with EPA or states.

1.1.4 Contents of the Manual

- Chapter 1 presents the purpose, scope, concept, and science/policy considerations, and the use of ERA in HTRW programs. It provides a description of the USACE HTRW program, quality required for performance of an ERA, and an understanding of how ERAs serve management decision needs. Relevant Federal statutes/regulations, agency guidance and directives, and state requirements are highlighted in this chapter.
- Chapter 2 presents the major scoping or project planning elements under CERCLA as amended by the Superfund Amendments and Reauthorization Act (SARA) of 1986, and RCRA as amended by the Hazardous and Solid Waste Amendments (HSWA) of 1984. Particular emphasis is placed on the early development of an ecological conceptual site model (ECSM) in the data quality design process to identify data needs, optimize data collection efforts, and recommend options for site decisions.
- Chapters 3 through 8 are intended to provide the risk assessor with the minimum requirements expected to be included in the ERA to adequately serve site decision requirements. They summarize the key components of the baseline ERA and other risk analyses. A running case study is presented throughout these chapters and Chapter 9 to explain key steps in an ERA and to demonstrate how risk management decisions may be made at each project phase in the HTRW program.
- Chapter 9 presents the information for risk management decision-making by focusing on the decision statements specific to the regulatory program and project phase, and criteria for decisions.
- Figures, tables, exhibits, and a continuous case study designed to illustrate or enhance readers' understanding of the materials are presented throughout. A glossary is presented also.
- Appendices A and B contain publication information for the references cited in the manual and additional sources of information, respectively.

Appendices C through H contain information that will be helpful to users of the manual in the preparation of ecological risk assessments.

1.2 USACE Role in the HTRW Program

In the execution of USACE environmental missions, the HTRW program is organized and staffed to respond to assignments for the following national environmental cleanup programs:

- EPA Superfund Program (a.k.a. CERCLA).
- Defense Environmental Restoration Program (DERP):
 - Installation Restoration Program (IRP).
 - Formerly Used Defense Sites (FUDS).
 - Department of Defense and State Memorandum of Agreement/Cooperative Agreement Program (DSMOA/CA).
- Base Realignment **and** Closure (BRAC).
- Environmental Compliance Assessment System (ECAS) (USACE 1992a).
- HTRW environmental restoration support for Civil Works projects and other Federal agencies (Department of Defense [DOD] and non-DOD).

For the purpose and intended use of this risk assessment manual, the focus is on the DERP and BRAC cleanup programs to address CERCLA- and RCRA-related issues.

1.2.1 DERP

DERP, codified in 10 USC Chapter 160, provides central program management for the cleanup of DOD hazardous waste sites consistent with the provisions of CERCLA. The goals of the program are: (1) the identification, investigation, research, and cleanup of contamination from hazardous substances; (2) correction of other environmental damage which creates an imminent and substantial endangerment to the public health and welfare, or to the environment; and (3) demolition and removal of unsafe buildings and structures.

1.2.2 BRAC

BRAC is an environmental restoration program with the mission to restore or clean up Army installations in preparation of real property disposal or transfer. The Base Closure Account (BCA), authorized under the Defense Authorization Amendments and Base Closure and Realignment Act of 1988 and the Defense Base Closure and Realignment Act of 1990, funds the BRAC program, which defines the nature and scope of contamination, performs remedial action, and documents the condition of real property by issuance of the Finding of Suitability to Lease (FOSL) (DoD 1993) and the Finding of Suitability to Transfer (FOST) (DoD 1994a). The Community Environmental Response Facilitation Act (CERFA) (Public Law 102-426) amends CERCLA Section 120(h) and requires Federal agencies to define "real property" on which no hazardous substances and no petroleum products or their derivatives were stored for one year or more, known to have been released, or disposed of before the property can be transferred. Transfer of contaminated property is allowed as long as the remedial action to clean up the site is demonstrated to be effective to EPA.

1.2.3 Others

Other components of the USACE HTRW program include:

- EPA Superfund Program Support -- Through an Interagency Agreement (IAG) and upon EPA request, USACE acts as the Federal government's contracting officer in conducting "Federal Lead" remedial design and construction activities. USACE may also provide other technical assistance to EPA in support of response actions.
- DSMOA/CA -- DoD reimburses states and territories up to one percent of the costs for technical services for environmental restoration cleanups. USACE is responsible for execution of activities which include establishing, managing, implementing, and monitoring the DSMOA/CA program.
- Non-Mission HTRW Work for Others -- Through IAG, non-DOD Federal agencies utilize the technical expertise and experience in work

relating to the RCRA, CERCLA, and underground storage tank (UST) investigation and response actions under the HTRW program for non-DOD Federal agencies.

- Guidance for Civil Works Projects -- The Civil Works districts may request technical support and guidance from HTRW program elements.

1.2.4 HTRW Program Organization

OM 10-1-1 (HQUSACE, October 31, 1990) and USACE HTRW Management Plan (USACE 1992b) describe the USACE organizational elements in support of DERP, BRAC, and other programs. Their major responsibilities include, but are not limited to, the following:

- The Assistant Secretary of the Army for Installations, Logistics, and the Environment (ASA (I,L,E))
- Headquarters, U.S. Army Corps of Engineers (HQUSACE) -- The Military Programs Directorate -- Environmental Restoration Division (CEMP-R) develops, monitors, coordinates, and proposes program management policies and guidance, and provides funding and manpower requirements to the program customers.
- The Director of Environmental Programs (DEP) within the office of the Assistant Chief of Staff for Installation Management (ACSIM) is responsible for interfacing with Department of Army (DA) components for policies and funds for IRP/FUDS/BRAC executed by USACE.
- HTRW Center of Expertise (CX) has the primary responsibility for maintaining state-of-the-art capability, providing technical assistance to other USACE elements, providing mandatory review of designated HTRW documents, and, as requested, providing technical and management support to HQUSACE.
- Ordnance and Explosives (OE) CX has the primary responsibility for maintaining state-of-the-art technical capabilities in OE, performing site inspections, engineering evaluations and cost analyses (EE/CA), and removal design phases of OE projects.
- Divisions are responsible for providing program oversight of all HTRW environmental restoration

projects and designating project management assignments for HTRW projects.

- HTRW Design Districts provide the Division Commander with technical support in the areas of health and safety, chemical and geotechnical data quality management, environmental laws and regulations, risk assessment, contracting and procurement, and technical design and construction oversight.

1.3 Overview of HTRW Response Process

HTRW response actions involve all phases of a site investigation, design, remediation, and site closeout. The HTRW response process is generally comprised of six executable phases or steps, once the HTRW response site has been identified. They are:

- Preliminary Assessment (PA).
- Site Inspection (SI).
- Remedial Investigation (RI), including Baseline ERA.
- Feasibility Study (FS).
- Remedial Design/Remedial Action (RD/RA).
- Site Closeout.

The HTRW response action process is phased and performed in accordance with EPA procedures for assessing uncontrolled hazardous waste sites under CERCLA or RCRA. The following sections generally describe the CERCLA and RCRA processes, which are functionally equivalent to one another in objectives and types of site decisions to be made throughout each process.

1.3.1 CERCLA Process

CERCLA, commonly known as "Superfund," establishes a national program for responding to uncontrolled releases of hazardous substances into the environment. The regulation implementing CERCLA is the **National Oil and Hazardous Substances Pollution Contingency Plan** (NCP) (40 CFR 300, EPA 1990a). In general, the CERCLA process consists of the site assessment phase and the remedial phase as described below; however, removal actions (as allowed by the NCP) may be taken at any time during the CERCLA process. It should be noted that

the general framework established under the CERCLA process has been adopted for use in environmental cleanup under other programs, e.g., the cleanup of petroleum, oil, and lubricants (POLs) at FUDS or active installations not listed on the proposed or final National Priorities List (NPL). Therefore, certain CERCLA project phases described below (specifically, the Hazard Ranking System [I-IRS], NPL, and site deletion), are not applicable to these types of facilities.

1.3.1.1 Site Assessment Phase - To Identify Sites for Further Evaluation

- **Site Discovery** - EPA identifies and lists in the CERCLA Information System (CERCLIS) possible hazardous substance releases to be evaluated under Superfund.
- **PA** - While limited in scope, a PA is performed on sites listed in CERCLIS to distinguish sites which pose little or no threat to humans and the environment and sites that require further investigation or emergency response.
- **SI** - An SI identifies sites which (1) have a high probability of qualifying for the NPL or pose an immediate health or environmental threat that requires a response action, (2) require further investigation to determine the degree of response action required, and/or (3) may be eliminated from further concern.
- **HRS** - At the end of both the PA and SI, EPA applies a scoring system known as the I-IRS to determine if a site should receive a “no further remedial action planned” recommendation or be listed on the NPL for further action. An I-IRS can also be used to support other site evaluation activities under CERCLA (see ***The Revised Hazard Ranking System: Background Information***, frtEPA 1990b). I-IRS scoring, however, is usually not applied at Federal facilities, especially for facilities within the IRP Program.

DoD (1994b) has developed ***the Relative Risk Site Evaluation Primer*** to rank sites primarily for resource allocation and program management purposes. Although not a replacement nor alternative for I-IRS scoring, this model suggests that

stakeholders consider evaluation factors (contaminant hazard factor, migration pathway factor, and receptor factor) to categorize sites according to “high,” “medium,” and “low.”

- **NPL** - Sites placed on the NPL (based on an HRS score of 28.5 or greater, state nomination, issuance of a health advisory by the Agency for Toxic Substances and Disease Registry (ATSDR), or other method) are published in the Federal Register and are eligible for Superfund-financed remedial action. DoD sites on the NPL, although not eligible for Superfund-financed remedial action, are eligible for Defense Environmental Restoration Account (DERA)-funded response actions.

1.3.1.2 Remedial Phase - To Determine the Degree of Risk Based on Nature and Extent of Contamination and Implement Cleanup Remedies if Warranted

- **RI** - The RI is a field investigation to characterize the nature and extent of contamination at a site and implement cleanup remedies if warranted. A baseline risk assessment, which includes both a human health risk assessment and an ERA, is performed as part of the RI. The baseline risk assessment is a component of the RI/FS report.
- **FS** - Based on data collected during the RI, remedial alternatives are developed, screened, and analyzed in detail. After potential alternatives are developed, the alternatives are screened against three broad criteria: effectiveness, implementability, and cost. Those alternatives which pass this initial screen will be

¹ *The Relative Risk Site Evaluation Primer* (DoD 1994b) has replaced the Defense Prioritization Model (DPM) which has features comparable to the HRS. DPM was used to predict whether the site may be a candidate for NPL listing or should receive priority funding under DERP.

further evaluated according to the nine criteria² and other risk management considerations not included in the criteria (e.g., environmental justice under Executive Order 12898) before one or more of such remedies is proposed for selection.³

- **Proposed Plan/Record of Decision (ROD)** - After the RI/FS process has been completed, a Proposed Plan is made available for public comment. The Proposed Plan identifies the remedies for the site jointly selected by the lead agency and the support agencies, and indicates the rationale for the selection. All final decisions and response to public comments are entered in a legal administrative record, the ROD.⁴
- **RD/RA** - RD is a subactivity in remedial implementation where the selected remedy is clearly defined and/or specified in accordance with engineering criteria in a bid package, enabling implementation of the remedy. RA is a subactivity in remedial response involving actual implementation of the selected remedy.
- **Five Year Review/Site Deletion** - Upon completion of all remedial actions, CERCLA and the NCP allows for the reclassification or deletion of the site from the NPL. If a remedial action results in any hazardous substances remaining on site, CERCLA Section 121(c) requires a review of the remedy once every five years to assure that: (1) the site is maintained, i.e., the remedy (including any engineering or institutional controls) remains operational and functional; and (2) human health/environment is protected, i.e.,

the cleanup standards (based on risk or ARARs) are still protective.

1.3.1.3 Removal Action - To Prevent, Minimize, Stabilize, or Mitigate Threat to Humans and the Environment

CERCLA Section 104 Removal Actions can take place at anytime during the entire CERCLA process. Unlike RAs, removal actions are not designed to comprehensively address all threats at the site. Removal actions may be emergencies (within hours of site discovery), time-critical (initiated within 6 months), nontime critical (planning for the removal action takes 6 months or longer), or early actions. Engineering evaluations and cost analyses (EE/CAs), comparable to FS, are required for removal actions that are deemed to be non time-critical.

1.3.2 RCRA Corrective Action Process

RCRA requires corrective action for releases of hazardous waste or hazardous waste constituents from Solid Waste Management Units (SWMUs) at hazardous waste Treatment, Storage and Disposal Facilities (TSDF) seeking an RCRA permit or approval of final closure. The owner or operator of a facility seeking a RCRA permit must:

- Institute corrective action as necessary to protect human health and the environment from all releases of hazardous waste and hazardous constituents from any SWMU at the facility.
- Comply with schedules of compliance for such corrective action.
- Implement corrective actions beyond the facility boundary.

The corrective action process has four main components: a RCRA Facility Assessment (RFA); a RCRA Facility Investigation (RFI); a Corrective Measures Study (CMS); and Corrective Measures Implementation (CMI).

- **RFA** - An RFA is designed to identify SWMUs which are, or are suspected to be, the source of a release to the environment. The RFA begins with a preliminary review of existing information on the facility, which may be followed by a visual site inspection. The RFA will result in one or more of these actions: (1) no further action is required; (2) an RFI is to be conducted to further investigate the documented

² The nine criteria are (1) overall protection of human health and the environment, (2) compliance with applicable or relevant and appropriate requirements (ARARs), (3) long-term effectiveness/permanence, (4) short-term effectiveness, (5) reduction of toxicity, mobility, or volume, (6) implementability, (7) cost, (8) state acceptance, and (9) community acceptance.

³ If the RI shows no unacceptable risk, regulators may agree to eliminate the FS and proceed directly to a no-action proposed plan.

⁴ OSWER has published several Directives for RODs. Further information on these can be found in the USACE (1995b) Technical Project Planning Guidance document.

or suspected releases; (3) interim measures are necessary to protect human health or the environment; and (4) referral to other authorities to address problems related to permitted releases.

- **RFI** - An RFI may be required based on the outcome of the RFA. An RFI is accomplished through either a permit schedule of compliance or an enforcement order. The extent of this investigation can range widely from a small or specific SWMU study to an Area of Concern (AOC). Results of the RFI will result in one or more of these actions: (1) no further action is required; (2) CMS is necessary; (3) interim corrective measures are necessary; or (4) referral to another authority to address problems related to permitted releases.
- **CMS** - A CMS is an “engineering evaluation” designed to evaluate and recommend the optimal corrective **measure(s) at each SWMU or CAMU where** contaminant levels are found in excess of screening “action levels” (developed during the RFI). Medium-specific cleanup levels protective of human health and ecological receptors are developed, and the boundaries or point(s) of compliance are set. At this project phase or before the CMI phase, RCRA provides the designation of a CAMU or TU in which remediation wastes **may be moved and managed** (according to the approved corrective measures) without triggering land disposal restriction regulations under 40 CFR Part 268. The remedy selected from all potential remedial alternatives, including the “no further action” alternative, should be based on four criteria:
 - Protection of human health and the environment
 - Attainment of media cleanup standards
 - Control of sources to eliminate harmful releases
 - Compliance with RCRA’s waste management and disposal requirements
- **CMI** - A CMI includes the actual design, construction, operation, maintenance, and periodic evaluation of the selected corrective measures.

EPA can impose interim corrective measures on RCRA facilities under corrective action to protect human health

and the environment. The interim corrective measures can be taken at any time during the corrective action process.

EPA is accelerating cleanups at RCRA corrective action sites by promoting the reduction of exposure and further releases of hazardous constituents until long-term remedies can be selected. These accelerated cleanup actions are known as “Stabilization Initiatives” and are similar in concept and application to the Super-fund Accelerated Cleanup Model (SACM) under CERCLA.

1.3.3 Functional Equivalency of CERCLA and RCRA Corrective Action Processes

The RCRA and CERCLA programs use different terminology but follow parallel procedures in responding to releases. In both programs. The first step after discovery of a site is an examination of available data to identify releases needing further investigation. This step is called PA/S1 in the CERCLA process and RFA in the RCRA process. If imminent human health and/or environmental threats exist, a mitigating action is authorized. known as a removal action under CERCLA Section 106 or an interim measure under RCRA Section 7003 or 3005(c)(3). Both programs require an in-depth characterization of the nature, extent, and rate of contaminant releases, called an RI in the CERCLA process and an RFI in the RCRA process. This is followed by a formal evaluation and selection of potential remedies in the FS (CERCLA) or CMS (RCRA) project phase. The selected remedy is executed by an RD/RA under the CERCLA process or CMI under the RCRA process. A specific discussion of the functional equivalency of both programs is presented in the preamble discussion of the July 27, 1990, proposed rules for Corrective Action for SWMUs at Hazardous Waste Management Facilities. A diagram comparing the RCRA and CERCLA processes is presented in Figure i-l.

1.3.4 Role of Risk Assessment in the HTRW Process

Performing an ERA is an iterative process. Risk assessment information is continuously being collected during the HTRW site investigation process, leading to the characterization of risks and uncertainties qualitatively or quantitatively. Risk assessment information is used in various stages of the HTRW site decision process as described below:

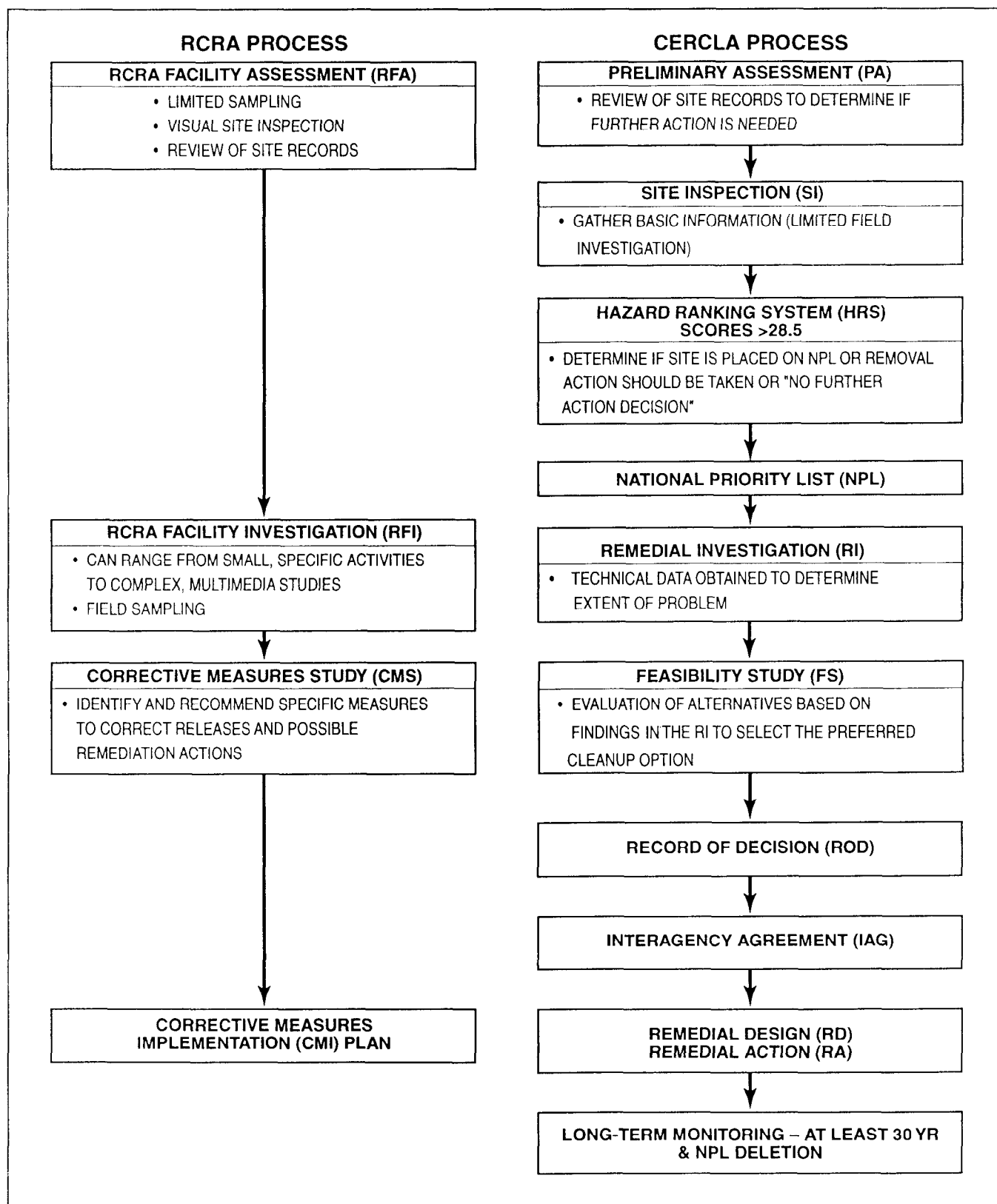


Figure 1-1. Comparison of RCRA and CERCLA processes

1.3.4.1 PA/SI, RFA, or Other Preliminary Site Investigation Activities

In this phase of the site investigation process, risk assessment information is used to: determine whether a site may be eliminated from further concern; identify emergency situations which may require immediate response actions/interim corrective measures; assess whether further site investigations are required; develop a data collection strategy; and set site priority, e.g., to rank sites.

The screening risk assessment developed during this phase should be conducted using conservative scenarios, as guided by the preliminary ECSM, to ensure that any closeout decision at the PA/SI stage is protective. The PA/SI ERA screening study is not to be confused with Preliminary Natural Resource Surveys (PNRSs), which are simple screening studies conducted by natural resource trustees in conjunction with an NRDA. If release of hazardous substances appears to have resulted in natural resource damage, then Section 122(j) of the amended CERCLA requires Federal natural resource trustees to be notified. Section 122(j)(1) encourages Federal natural resource trustees to participate in response and remedy negotiations, so that data collected in an ERA can be used by the trustees in carrying out their responsibilities.

1.3.4.2 RI, RFI, or Other Additional Site Investigation Activities

Data collected in this phase should comprise those media and pathways identified in the preliminary screening, including background data. If the data are useable and appropriate for the potential exposure pathways considered to be complete, a baseline ERA can be developed. The baseline ERA will identify whether unacceptable ecological risks are posed by existing conditions at the site.

For assessing ecological risks, data should be collected in the boundary or study area of ecological concern and may need to be collected in reference areas as well. The study area may necessitate combining SWMUs or operable units (OUs) or developing a base-wide ERA if such combination is consistent with the ECSM for assessing contamination and remediation options. Combined OUs or SWMUs should be discussed with the regulators and identified in the agreements with agencies, the work plan, or other decision documents.

1.3.4.3 FS, RD/RA, CMS/CMI, or Other Remedial Design and Implementation Activities

The baseline ERA completed in the RI serves to identify the need for response actions and the relative degree of response required. The potential human/environmental impacts posed during remediation (short-term and long-term) and the residual risks after remediation are evaluated during remedy selection.

1.3.4.4 Use of Risk Assessment in Special Studies

The following are examples of ERAs used in special studies:

- ARAR Waiver - If a site-specific alternate remedial action objective developed from the ERA is as protective as a particular ARAR, an ARAR waiver request may be submitted under CERCLA Section 121(d)(2). The same process may be used to waive state ARARs.
- Emergency Response - The effectiveness of a proposed removal action, particularly for non-time critical response action, can be evaluated by the ERA in terms of the ability of the action to reduce exposure or risks.
- Biological Assessment of Endangered Species - The Endangered Species Act (ESA) requires the preparation of a biological assessment if Federally listed endangered or threatened species or their habitat could be impacted by the contaminants or cleanup actions (e.g., incinerator emissions) at hazardous waste sites. The ERA for the endangered or threatened species, and optional assessment of the Category 2 and rare species, may satisfy the draft and final biological assessment requirements (Section 7 consultation) of U.S. Fish and Wildlife Service (USFWS) or other trustee agencies.

1.4 Concept of Risk Assessment and Good Science

Risk assessment can be qualitative or quantitative. It includes an integration of hazard (chemical or nonchemical), exposure (scenario and pathways), exposure-response (relationship between the magnitude of exposure and the

resulting ecological effects), and characterization of the risks and uncertainties. The risk assessment process relies on strong fundamental scientific principles and representative data. Despite this effort, there will be unavoidable data gaps and uncertainties where scientific and professional judgement is needed to predict or infer certain outcomes under certain scientific principles (Federal Focus Inc. 1994). The application of such judgement requires that the risk assessor provide the rationale or basis for the judgement. This view is reflected by the recent Policy for Risk Characterization (EPA 1995a) and NRC's (1993) Science and Judgement in Risk Assessment. Both EPA and NRC recognize the inherent uncertainties in the risk assessment methodologies and the need for making risk assessments more transparent, clear, consistent, and reasonable.

This section highlights the principles, instructions, or recommendations for assessing ecological risks from potential COECs⁵ in environmental media at HTRW sites. A more in-depth discussion of the various risk assessment components and issues relating to HTRW response actions is presented in Chapter 4.

The fundamental principles of "good science" entail the thorough understanding of (1) site chemical data; (2) physical, chemical, and ecotoxicity information associated with site chemicals; (3) fate and transport modeling; (4) bioavailability and extent of uptake or bioconcentration; (5) the exposure-effects relationship of site chemicals and underlying uncertainties/conservatism; (6) uncertainties and limitations of the derived risk estimate; (7) the correct interpretation of previously collected data, considering confounding factors, and making objective inferences or test hypotheses; and (8) unbiased presentation of findings and limitations or uncertainties associated with the findings. This section concludes by identifying the minimum requirements for a risk assessment under the "good science" concept.

1.4.1 Basic Concepts

An open and unbiased ERA allows risk managers to make informed site decisions. The concept of "risk assessment" is presented in the following questions and answers:

⁵ Chemicals of potential ecological concern (COPEC) may also be used instead of potential COECs. The term "potential" should be used throughout the course of the ERA, until the chemicals are determined to be or not to be of concern. In this manual, the term potential is generally implied wherever COEC is used.

What is a risk assessment?

A risk assessment is an evaluation of the potential adverse impact of a given activity or a lack of activity upon the well being of an individual, a population, a community, or an organization. It is a process by which information or experience concerning the cause and effect under a set of circumstances (exposure) is integrated with the extent of exposure in order to assess risk. RAGS II (EPA 1989a) defines an ERA as a qualitative and/or quantitative appraisal of the actual or potential effects of a hazardous waste site on plants and animals other than people or domesticated species (EPA 1989a). EPA (1994a) further defines an ERA as an estimate of the likelihood that adverse ecological effects (e.g., mortality, reproductive failure) will occur as a result of a release of a hazardous substance at a Superfund site. EPA (1994a) states the purpose for conducting the ERA is to "(1) identify and characterize the current and potential threats to the environment from a hazardous substance release, (2) evaluate the ecological impacts of alternative remediation strategies, (3) establish clean-up levels in the selected remedy that will protect those natural resources at risk."

Generally, an ERA consists of a three-step process:

- **Problem Formulation** - specify objectives and scope; identify preliminary remediation goals; qualitatively evaluate contaminant release, migration, and fate; identify potential COECs, exposure pathways, receptors, and known effects; develop a preliminary ECSM; and select ecological endpoints.
- **The Analysis Phase**, which is comprised of two major elements:
 - **Exposure Characterization** - quantify contaminant release, migration, and fate; characterize receptors; measure or estimate exposure point concentrations; and refine the ECSM regarding the relationships among trophic levels in the food web model.
 - **Effects Characterization Assessment** - review ecotoxicity information from

literature, toxicity testing, and field studies; and assess nonchemical impacts or potential adverse health impacts from remediation.

- **Risk Characterization** - present findings qualitatively or quantitatively with regard to the potential impacts to individuals, populations, communities, or other ecosystem components of concern from a single chemical or multiple chemicals from one or more site media, based upon the review of exposure assessment and exposure-response information. A candid discussion of the uncertainty associated with the risk characterization findings is an essential component of this step. This step focuses on the significance of the impact, causal association or weight-of-evidence, and sources of uncertainty.

Why use risk assessment in site decisions?

- Risk assessment can identify sites in the SI or RFA stage that warrant no further evaluation.
- Risk assessment provides a tool that enables risk managers to determine if remediation is warranted and to prioritize those sites requiring remediation.
- CERCL/SARA requires that remedial actions assure “protection of human health and the environment” against contaminants that “will, or may reasonably be anticipated to cause” certain adverse health effects, and must under certain circumstances meet standards set under other Acts...” The NCP provides for the use of risk assessment in removal actions, remedial actions, and remedy selection. Consistent with the NCP, the SACM at EPA requires site screening, risk assessment, and early action to reduce immediate risk for removal/immediate response actions.
- RCRA/HSWA establishes EPA programs to control disposal of solid wastes which “may cause, or significantly contribute to an increase in mortality or . . . serious irreversible, or incapacitating reversible, illness; or . . . pose a substantial present or potential hazard to human health or the environment” or which “endanger health [when present in excess of certain levels].” The RFI Guidance (EPA 1989b) provides general procedures for performing a health assessment and an environmental assessment. The Corrective Action Rule (RCRA Subpart S) also provides the use of a

site-specific risk assessment to evaluate SWMUs or the CAMUs under enforcement actions or Part B permitting.

What are the minimum requirements of information in the risk assessment?

- Specification of which chemicals are of particular concern from an ecological perspective and what are the mechanisms for their release and transport (chemical abstract numbers should be provided).
- Environmental setting, and potential/reasonably anticipated land use.
- Potential receptors and populations, and the relationships of organisms/populations among different trophic levels in a community or ecosystem.
- Complete and significant exposure pathways.
- Reasonably assumed chemical uptake, bioaccumulation in the individual and biomagnification in the ecosystem under short-term and long-term exposure conditions.
- Adverse ecological effects for ecological receptors that are measurable and can be appropriately related back to the assessment endpoints.
- Uncertainties and limitations of the risk assessment, expressed either qualitatively or quantitatively.
- Chemicals and exposure pathways which contribute the most risk (pose the principal threat).
- Protectiveness of remediation goals and health impacts of the removal/remediation actions.

Throughout this manual, there are references to uncertainties in a risk assessment and the use of good science to plan and execute a site-specific baseline ERA. Clarifying the meaning of these terms will help readers who are responsible for scoping, planning, and reviewing a baseline risk assessment. The existence of uncertainties in a risk assessment and the importance of good science are explained in the following questions and answers:

How do “uncertainties” impact a risk assessment?

- The application of sound scientific principles is critical to assessing risks. Only rarely do sufficient data exist to accurately define the extent of exposure and the resulting ecological effects. Therefore, an ERA is frequently performed with assumptions, empirical models, extrapolations, test of hypotheses, and inferences of results which have a certain level of uncertainty. Many times, conservative assumptions are used in models relating to exposure and toxicity that characterize ecological risk. These assumptions add another degree of uncertainty to risk assessment. For these reasons, the predicted ecological effects experienced by the individuals, populations, and/or community could be higher than the current or future observed effects. This conservatism may unnecessarily result in environmental cleanup with little or no measurable environmental benefits and can divert resources from higher priority projects.

What is meant by “good science” in a risk assessment?

- Risk assessment as a “scientific” endeavor should be objective to assure that the assessment is specific to the site, is based on sound scientific principles, and is defensible. However, a risk assessment often requires use of “professional judgement” when data are lacking, lends itself to interpretation, often uses assumptions and generalities, and may easily become nonobjective. Bias or lack of scientific objectivity can cause the risk results to over- or under-estimate the true risks. This may result in costly delays or inappropriate inaction/action. Therefore, a peer review process should be incorporated in various phases of the risk assessment, and care should be given early in the scoping and planning process to collect data and specify requirements in performing a risk assessment under the HTRW program. Persons performing the risk assessment should have a good understanding of the site and should possess the basic skills needed to plan, collect, and interpret the information.

1.4.2 Risk Assessment as Decision Criteria in the HTRW Program

The role of a risk assessment in the site decision-making process at CERCLA and RCRA Corrective Action sites

has been well defined by EPA either through rule-making or program directive/guidance. Therefore, risk assessments have been used as decision criteria in the USACE’s HTRW program involving CERCLA and RCRA sites. For BRAC, FUDS, or other HTRW work which may not be on the NPL, risk assessments should be similarly applied. Activities at these sites require the evaluation of potential health and environmental risks in order to return the property to conditions appropriate for the current and planned future land uses. Therefore, a site-specific baseline risk assessment is an important decision tool for USACE customers. If cleanup is needed, the extent or level of cleanup required will be based on results of the baseline risk assessment, in addition to ARARs or other nonrisk factors. Therefore, risk assessment is used as a decision tool at all HTRW response action sites.

DOD and other Federal agencies recognize the need for early input from all stakeholders (broadly defined as the regulators, concerned citizens, environmental groups, and other appropriate public and private interested parties) in order to facilitate risk management decision-making. Establishing an early dialogue with stakeholders is particularly important for ERAs in the project planning phase to develop assessment strategies and preliminary remedial action objectives.

1.5 Policy Considerations and Risk Management

This section presents a general discussion of the influence of policy considerations in risk assessment and risk management. Because of the implications of policy considerations on the site decision process, the risk assessors and risk managers are encouraged to identify the policies early in the decision process.

Unlike regulations which are enforceable, policies or published guidelines are administrative procedures or requirements concerning certain environmental regulations. DOD has issued directives to components (Army, Navy, Air Force, Defense Logistic Agency, and Defense Nuclear Agency), reaffirming DOD’s commitment to comply with specific environmental laws or executive orders. The respective components have also issued directives or orders expressing the same procedures or requirements. USACE will follow such policies or directives issued by DOD or its components regarding compliance with Federal environmental laws in the execution of HTRW response action at DOD installations or facilities. Some states or regional environmental control boards have also issued environmental policies or guidance. In the unlikely event that a policy is scientifically incongruent with site situations, early identification and

resolution are critical. HQUSACE or HTRW CX technical staff should be consulted in these instances. All major policies used in making site decisions should be identified in the ROD or site decision documents so that the USACE customers and other stakeholders can judge the merit of these policies in achieving protection of human health and the environment.

1.5.1 Relationship Between Policy Considerations and Risk

A risk assessment is the technical evaluation of the degree of hazard or risk associated with exposure of a receptor or receptor populations to contamination of an environmental medium or media. Risk management is oriented toward deciding whether remedial actions are warranted in light of the results of a risk assessment. The National Academy of Sciences (NAS) National Research Council (NRC) defines risk management as “the process of weighing policy alternatives and selecting the most appropriate regulatory action, integrating the results of risk assessment with engineering data and with social, economic and political concerns to reach a decision” (NRC 1983). NAS has identified four key components in managing risk and resources: public participation, risk assessment, risk management, and public policy decision-makers (NRC 1994).

In making risk management decisions, the risk manager considers the degree of risk, technical feasibility to address risk, costs and benefits, community acceptability, permanence of the proposed actions, and other similar factors which are subject to policy considerations or regulatory requirements. As such, risk management is an important part of the USACE HTRW site response process, as it combines results of the risk assessment, regulatory requirements, and applicable agency policies (e.g., applicable DoD policies for defense sites).

1.5.2 EPA Headquarters, Regional, and State Policies

To successfully complete a risk assessment for use in making site decisions, HTRW project managers and risk assessors generally work with Federal, regional, and state regulatory agencies to identify their specific policies or procedural requirements. HTRW risk assessors should identify and assist, where appropriate, in negotiations with the agencies on policies, procedures, and assumptions which are questionable.

All HTRW response actions should be in compliance with the Regulatory Policy Guideline issued under Executive

Order 12498 (1985) Government Management, which states, “Regulations that seek to reduce health or safety risks should be based upon scientific risk assessment procedures, and should address risks that are real and significant rather than hypothetical or remote.” USACE’s HTRW position should be supported by scientific principles, site data, or literature values, whenever possible. USACE recognizes that at times, agencies have to set policies in the absence of scientific consensus: however, USACE, through the HTRW program, has the responsibility to apply such policies properly and objectively based on site-specific considerations.

1.5.3 Risk-Based Management Decisions for Site Actions

Risk managers select the most appropriate remedy by considering “trade-offs” among different remedial alternatives and evaluating the ability of the alternatives to accomplish the overall project objectives. To improve the quality of risk-based management site decisions, HTRW risk assessors should identify key information that can affect that decision-making. This information should include policy considerations, assumptions concerning the margins of safety, and the use of other relevant data not associated with the site in the risk assessment. The sources of such policies and data, as well as the qualifications of persons/organization recommending the policies or use of data, should be clearly identified. HTRW risk assessors can further help risk managers by providing an explanation of uncertainties in the risk assessment. When science deviates from policies or assumptions inherent in the risk assessment, it is the responsibility of HTRW risk assessors to clearly identify these instances as potential uncertainties as well.

1.6 Regulatory Directives and Guidance

This section highlights major executive orders, Federal statutes/regulations under which the HTRW programs operate, and EPA risk assessment guidelines which provide the basis for development of this manual. Irrespective of the procedures or mechanics for conducting risk assessments according to regulatory guidelines, all risk assessments performed under the HTRW response action must be based on “good science” and reasonable and unbiased scientific judgment. Although this section lists only major applicable executive orders and directives, others may be accessed through the appropriate agencies and databases on Internet (see Appendix B).

1.6.1 Executive Orders and Federal Statutes/Regulations

Executive Order 12088 (1978), **Federal Compliance with Pollution Control Standards**, established the mechanism by which the Executive Branch assures that its facilities (in various departments) meet their compliance responsibilities by complying with substantive and procedural requirements of Federal environmental statutes. These statutes include: Endangered Species Act (ESA), the Clean Air Act (CAA); the Federal Water Pollution Control Act (Clean Water Act); the Solid Waste Disposal Act (as amended by RCRA); the Noise Control Act; the Marine Protection, Research and Sanctuaries Act (Ocean Dumping Act), the Safe Drinking Water Act (SDWA), the Toxic Substances Control Act (TSCA), the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), the National Historic Preservation Act (NHPA), and the National Environmental Policy Act (NEPA).

Executive Order 12498 (1985), **Government Management**, incorporates by reference the regulatory principles contained in a Task Force report regarding future significant regulatory actions. Two principles of interest are:

- Regulations that seek to reduce health or safety risks should be based upon scientific risk-assessment procedures, and should address risks that are real and significant, rather than hypothetical or remote.
- To be useful in determining overall benefits and costs, risk assessments must be scientifically objective and include all relevant information. In particular, risk assessment must be unbiased best estimates, not hypothetical “worst cases” or “best cases.” ... In addition, the distribution of probabilities for various possible results should be presented separately, so as to allow for an explicit “margin of safety” in final decisions.

Executive Order 12580 (1987), **Superfund Implementation**, requires all Federal agencies to comply with CERCLA/SARA and NCP in the same manner as the private sector. This Order delegated to the Secretary of Defense the response authority of DoD, which includes removal/remedial actions, site investigation and risk assessment, remedy selection, performance of PAS, and assuming natural resource trustee’s responsibilities for current and former DoD facilities, and others. The Office of the Deputy Under Secretary of Defense for Environment Security (ODUSD [ES]) is responsible for carrying the

Secretary’s responsibilities and administering DERPs in compliance with this Order.

Executive Order 12777 (1991), **Implementation of Section 311 of the Federal Water Pollution Control Act of October 18, 1972 and the Oil Pollution Act of 1990**. Delegates to the EPA and Coast Guard various responsibilities assigned to the President under Clean Water Act Section 311 and the Oil Pollution Act of 1990.

Other relevant Executive Orders include: Executive Order 11990 (1977), **Protection of Wetlands**, and Executive Order 11988 (1977), **Floodplain Management**.

NEPA 1969 provides a national framework for the protection of the environment by requiring compliance with a wide variety of existing environmental statutes. It mandates the Federal agencies “utilize a systematic, interdisciplinary approach that will ensure the integrated use of the natural and social sciences and the environmental design arts in planning and in decision-making, which may have an impact on man’s environment.” The implementing regulations for NEPA are found in 40 CFR 1500-1508, as promulgated by the Council on Environmental Quality.

It is, in essence, a planning tool for nonemergency environmental actions, through either justifications for categorical exclusions or through preparation and approval of NEPA documents (i.e., environmental assessment [EA] and environmental impact statements [EISs]). The NEPA documents evaluate alternatives and provide analysis on alternatives regarding their impacts on health, safety, and welfare of humans and the environment, including environmental justice in minority and low income populations. HTRW response actions, specifically removal and remedial actions, could be subject to NEPA review for the selection of alternatives. The implementing guidance for DoD for NEPA includes:

- DoD Directive 6050.1 (July 30, 1979a), **Environmental Effects in the United States of Department of Defense Actions**.
- DoD Directive 6060.7 (March 31, 1979b), **Environmental Effects Abroad of Major Department of Defense Actions**.
- Army Regulation 200-2 (1988), **Environmental Effects of Army Actions**.

RCRA 1976, as amended by the HSWA of 1984, has the objectives to protect human health and the environment,

reduce waste and conserve energy/natural resources, and reduce or eliminate generation of hazardous waste:

- Subtitle D - solid waste (encourages states to develop and implement solid waste management plans to provide capacity).
- Subtitle C - hazardous waste program (identifies hazardous wastes and regulates their generation, transportation, and treatment, storage, or disposal; authorizes states to implement the hazardous waste program in lieu of EPA: requires permits for TSDFs).
- Subtitle I - underground storage tanks (regulates petroleum products and hazardous substances stored in underground tanks: requires compliance with performance standards for new tanks: and requires leak detection, prevention, closure, financial responsibility, and corrective action).

CERCLA of 1980, as amended by the SARA of 1986 (42 U.S.C. 9601 et seq.) provides broad Federal authority to respond directly to releases or threatened releases of hazardous substances that may endanger public health or the environment. SARA defines the process Federal agencies must follow in undertaking remedial action, including a requirement that EPA make the final selection of remedy if there is a disagreement between the Federal agency and EPA.

The NCP (55 FR 8660, 9 March 1990) provides procedures and standards for how EPA, other Federal agencies, states, and private parties respond under CERCLA to releases of hazardous substances. The NCP authorizes the U.S. Department of the Interior (USDOI) and other agencies, states, or entities to be the “trustees” of natural resources to recover compensatory damages for “injury to, destruction of, or loss of natural resources resulting from a discharge of oil into navigable waters or a release of a hazardous substance.”

Federal Facility Compliance Act (PL-102386, October 21, 1992) directs Federal agencies to comply with Federal and state environmental laws, and provides authority to EPA to impose penalties on other Federal agencies for noncompliance. Among others, it amended Section 6001 of RCRA to waive immunity of the United States (Federal department, agency, or instrumentality of the United States) to administrative orders and civil penalties or fines associated with Federal, state, interstate, and local solid and hazardous waste management requirements. Section 3004 of RCRA was also amended to require EPA, in

consultation with DoD, to identify and regulate waste military munitions which are hazardous.

1.6.2 DoD Directives

DoD Directive 5100.50 (19731, *Protection and Enhancement of Environmental Quality*, establishes procedures and assigns responsibilities for use of DoD resources in the protection and enhancement of environmental quality and establishes the DoD Committee on Environmental Quality.

DoD Directive 5030.41 (1977a), *Oil and Hazardous Substances Pollution Prevention and Contingency Program*, sets forth DoD policy in support of the NCP.

DoD Directive 4120.14 (1977b) *Environmental Pollution, Prevention, Control, and Abatement*, implements within DoD new policies provided by Executive Order 12088 and Office of Management and Budget (OMB) Circular A-106, and establishes policies for developing and submitting plans for improvements needed to abate air and water pollution emanating from DoD facilities.

DoD Directive 6230.1 (1978), *Safe Drinking Water*, sets forth DoD policy for provision of safe drinking water and compliance with the SDWA.

DoD Directive 6050.1 (1979a), *Environmental Effects in the United States of DoD Actions*, implements the CEQ regulations and provides policies and procedures to take into account environmental considerations in DoD actions.

1.6.3 EPA Headquarters and Regional Guidance

CERCLA

Guidance documents (OSWER Directives) for conducting various phases of a CERCLA response action have been developed or are being finalized by EPA headquarters. Key CERCLA guidance documents are identified below (also see Appendix B):

- ***Guidance for Performing Preliminary Assessments Under CERCLA*** (EPA 199 la). This document provides the PA objectives, data requirements, the procedural steps to complete the PA, and develops a site score using PA scoresheets. It also provides guidelines for reviewing the site evaluation and score, including identification of sites for emergency response actions.

- **Guidance for Performing Site Inspections Under CERCLA** (EPA 1992b). This document provides the approaches, data acquisition planning needs, sampling strategies, data evaluations using the SI worksheets, and reporting requirements for the CERCLA SI. The document describes the approach of use of a focused SI to test the PA hypotheses, resulting in one of three recommendations: (1) site evaluation accomplished: (2) expanded SI to collect additional data: or (3) preparation of an FIRS package for placement of the site on the NPL if the HRS scoring data requirements have been met.
- **Hazard Ranking System Guidance** (EPA 1992c) provides guidance to individuals responsible for preparing HRS packages for sites for inclusion on the NPL.
- **Guidance for Conducting Remedial Investigations and Feasibility Studies Under CERCLA, interim final** (EPA 1988a). This guidance describes the CERCLA RI/FS process to characterize the nature and extent of contamination or risks posed by a site and to evaluate whether remedial action is needed. It describes the site characterization techniques, the role of a baseline risk assessment, feasibility studies, and development of screening and detailed analyses of remedial alternatives.
- **Guidance for Data Useability in Risk Assessment (Part A)** (EPA 1992d) and **(Part B)** (EPA 1992e). These guidance documents provide approaches and recommendations for defining, planning, and assessing analytical data for the baseline risk assessment.
- **Risk Assessment Guidance for Superfund, Volume II, Environmental Evaluation Manual** (RAGS II) (EPA 1989a) - The guidance consists of two parts: (1) a guidance manual that establishes a general framework for understanding the ecological principles of a Super-fund ERA and discusses the performance of the assessment, and (2) a compendium method handbook, **Ecological Assessment of Hazardous Waste Sites: A Field and Laboratory Reference** (EPA 1989c).
- **Eco Update** - Eco Update is a bulletin series on ecological assessments at Superfund sites. These bulletins serve as supplements to RAGS II and share information with the readers advisories involving the Biological and Ecological Technical

Assistance Groups (Biological Technical Assistance Groups [BTAGs], Ecological Technical Assistance Groups [ETAGs]), and other ERA and natural resource issues. The bulletin series is written for both general and technical audiences.

- **BTAG Forum** - BTAG Forum is a bulletin series published by EPA/OERR primarily to foster communication among BTAGs/ETAGs in EPA Regional Offices. The Forum carries news from the Regions, information on publications and other potentially useful resources, requests for information, and other items of interest to BTAG members.
- **Superfund Program Checklist for Ecological Assessment/Sampling** (EPA 1993a) - This checklist provides guidance on making observations during an ecological assessment and is a screening tool for preliminary site evaluation. The checklist is not intended to be used for limited actions nor for purely industrial settings with no discharges, but may be useful in planning more extensive site investigations.
- EPA Regional guidances - A number of EPA Regions and states have developed ERA guidance and specific protocols or approaches. Risk assessors should consult with the individual EPA Regions or states to obtain their specific guidances. For example, EPA Regions V and VI have published regional ERA guidance (EPA 1992f; EPA 1991b); EPA (1994b) Region III has issued Interim Ecological Risk Assessment Guidelines: and EPA Region IX is developing protocols for the evaluation of terrestrial indicators.

RCRA

Limited guidance has been developed for conducting various phases of a RCRA facility response action to address current or past releases. The key RCRA guidance documents that are available are identified below:

- **RCRA Facility Assessment Guidance** (EPA/530-SW-86-053) (EPA 1986a). Provides guidance for conducting facility assessments to reflect developments of the RCRA corrective action programs. Also clarifies the definition of an SWMU.

- **RCRA Corrective Action Interim Measures Guidance** (EPA/530-SW-88-029) (EPA 1988b). Assists EPA regions and states to perform corrective action interim measures to mitigate or remove an exposure threat presented by releases.
- **RCRA Corrective Action Plan** (EPA/530-SW-88-028) (EPA 1988c). Provides technical framework for development of Corrective Action Orders and corrective action permit requirements.
- **RCRA Facility Investigation (RFI) Guidance** (EPA 1989b). General guidelines for performing health and environmental evaluations are described in this four-volume guidance manual. With regard to performing environmental risk assessments, this guidance is substantively equivalent to RAGS and references the CERCLA methodology.

1.6.4 State Requirements/Guidance

HTRW risk assessors and project managers need to be aware of any risk assessment procedures, data needs, or programs specific to the state in which their site is located. Almost all states have been authorized for RCRA permitting; some have corrective action authorities. Many states have statutes and regulations that address uncontrolled hazardous waste sites and SWMUs associated with regulated RCRA facilities. Also, many states have primacy in the water pollution control program (under CWA) and have either adopted EPA criteria or developed their own water quality standards. Many states have adopted the use of risk assessment for corrective action, to demonstrate “how clean is clean,” to develop site-specific cleanup goals, to evaluate facilities burning hazardous waste, or for other uses.

Some states have developed specific guidance for assessing environmental impacts. For example, the New York Department of Environmental Conservation (NYDEC 1991) has developed *Fish and Wildlife Impact Analysis for Inactive Hazardous Waste Sites*. *Environmental Risk Characterization Guidance* is available from the Massachusetts Department of Environmental Protection (MDEP 1994). California Environmental Protection Agency has also developed its own guidance entitled, *Guidance for Ecological Risk Assessment at Hazardous Waste Sites and Permitted Facilities* (CAL EPA 1994). Pennsylvania’s Department of Environmental Resources (1991) has developed *Risk Assessment Guidelines for Facilities Burning Hazardous Waste*. Other states (Connecticut, Illinois, and

Kentucky) have adopted RAGS II, and in some cases, EPA regional guidance, as a matter of policy.

In addition to state rules, regional initiatives may exist that may need to be considered when performing an ERA. For example, EPA (1995b), in coordination with the Great Lakes states, undertook the Great Lakes Water Quality Initiative (GLWQI) and published the *Final Water Quality Guidance for the Great Lakes Systems* (60 FR 15366). The guidance specifies water quality criteria for the Great Lakes as well as specific water program requirements. The purpose of the guidance is to establish consistent water quality criteria within waters of the Great Lakes basin.

1.6.5 Others

U.S. Army (USA)

Army Regulation 200-1, *Environmental Quality, Environmental Protection, and Enhancement* (USA 1990), implements the Federal environmental laws and regulations at the Department of the Army facilities. Chapter 12-5, *Army Regulation 200-1 requires the performance of an Environmental Baseline Study for any property transaction*. DA PAM 40-578 (USA 1991), entitled *Health Risk Assessment Guidance for the Installation Restoration Program and Formerly Used Defense Sites*, presents the methodology used by the Army when reviewing health risk assessments, and designates the U.S. Army Center for Health Promotion and Preventive Medicine (USACHPPM) to oversee and recommend approval or disapproval to the Army Surgeon General on all human health risk assessments prepared by executing agencies for Army IRP sites, BRAC sites, and FUDS.

The U.S. Army Edgewood Research, Development, and Engineering Center (USAERDEC) (formerly the U.S. Army Chemical Research, Development, and Engineering Center) has developed the *Procedural Guidelines for Ecological Risk Assessment at U.S. Army Sites* (USAERDEC 1994). This guidance develops a standardized ERA procedure and tiered approach for assessing ecological risks.

Army Regulation 420-74, *Natural Resources -- Land, Forest, and Wildlife Management*, provides Army policy for managing natural resources and attaining the goal of ensuring that Army actions are not likely to jeopardize the continued existence of endangered or threatened species or result in the destruction or adverse modification of the critical habitat of such species.

U.S. Air Force (USAF)

The Office of the Air Force Surgeon General's Biomedical Engineering Service (BES) is responsible for providing technical support for all Air Force DERP CERCLA activities. The Air Force *Installation Restoration Program Management Guidance* (USAF 1989) and FY 93/94/95 *DERA Eligibility and Programming Guidance* (USAF 1992) provide guidance in this area. Work relating to hazardous waste management activities under RCRA is performed by the BES in accordance with Air Force Regulation 19-7 and *USAF Hazardous Waste Management Policy* (USAF 1991). Currently, the environmental service centers for USAF, such as USACE, or the risk assessors at respective Major Air Force Commands (MACOMs) review risk assessments in coordination with the Air Force Surgeon General.

The Human System Division IRP Office at Brooks Air Force Base, Texas, has developed the *General Guidance for Ecological Risk Assessment at Air Force Installations* (USAF 1990). The document provides an overview of the fundamentals of risk assessment and guidance for conducting an ERA. Guidance is provided for assessing the terrestrial, freshwater, and marine habitats.

U.S. Navy and Marine Corps

The Chief of Naval Operations directive OPNAVINST 5090.1B (DON 1994), Department of the Navy (DON), assigns command responsibilities and provides Navy policy to comply with environmental laws and regulations. The Navy and Marine Corps IRP Manual (DON/CNO 1992) describes the Navy organization/responsibilities in support of IRP, priority for funding, research, training, and reporting requirements including preparation of Pollution Control Report to satisfy the OMB Circular A-106 reports to EPA. The Naval Environmental Health Center, under the direction of the Bureau of Medicine and Surgery (BUMED), provides a wide range of medical consultative services to the Naval Facilities Engineering Command community in support of the IRP, the BRAC Program, and other related environmental projects. Consultative support services include but are not limited to review of IRP and BRAC program documents (e.g., work plans, sampling and analysis plans, quality assurance/quality control plans; remedial investigation/feasibility studies, risk assessments, health and safety plans) from a risk assessment and public health perspective: conducting risk evaluations or quantitative risk assessments; training in risk assessment, public health assessment, health and

safety plans, and risk communication: sponsoring the 3-day tri-service Environmental Risk Communication and Public Dialogue Workshop; negotiating with regulators regarding the use of realistic exposure assumptions; assisting in developing community relations plans; assisting in establishing Restoration Advisory Boards (RABs); assisting in preparing correspondence from a risk communication perspective; preparing posters for public exhibits and public meetings; and acting as the DON liaison for ATSDR issues.

U.S. Environmental Protection Agency (EPA)

EPA has published a number of enforcement policies and procedures for Federal facilities, e.g., *Federal Facilities Compliance Strategy* (EPA 1988d), *Enforcement Actions Under RCRA and CERCLA at Federal Facilities* (EPA 1988e), *Evaluation Process for Achieving Federal Facility Compliance* (EPA 1988f), *Federal Facilities Negotiations Policy* (EPA 1989d), and *Federal Facilities Hazardous Waste Compliance Manual* (EPA 1990c). All Federal agencies are required to comply with hazards waste regulations and the NCP in the same manner as the private sector. EPA has published numerous guidance and resource documents applicable to ERAS. Many of these references are presented in Appendix B.

U.S. Department of Energy

DOE has issued a number of orders (5400 series and others) addressing a variety of environmental statutes and requiring all DOE facilities to comply with applicable environmental laws and regulations. Some of the key DOE guidances are included in Appendix B.

U.S. Department of Commerce, National Oceanic and Atmospheric Administration (NOAA)

NOAA has published a manual entitled *The Coastal Resource Coordinator's Bioassessment Manual* (NOAA 1992). As a desk reference manual for coastal coordinators, this manual provides general guidelines on the application of bioassessment procedures to different stages of the hazardous waste site remedial process, the design of bioassessment studies, and use of specific bioassessment methodologies. In addition, a summary of recommended aquatic toxicity testing protocols is provided. NOAA (Long et al. 1995) has also published screening levels for chemical concentrations in marine sediments, based on studies at multiple sites in the marine and estuarine environments.

Canadian Council of Ministers of the Environment

Environment Canada (1994) has published a *Framework for ERA* and sediment screening values (CCME 1995). The Canadian province of Ontario has published sediment lower effect level (LEL) and severe effect level (SEL) values for the evaluation of marine and freshwater sediments (Persaud, Jaugumagi, and Hayton 1992, Long et al. 1995).

USFWS

USFWS published the Contaminant Hazard Review series between 1985 and 1994. This continuing series of reports reviews the hazards of specific toxic compounds to invertebrates and wildlife. Biological Report 90(2) summarizes data on soil toxicity for screening assessment for terrestrial systems (Beyer 1990).

Water Environmental Research Foundation (WERE)

WERF (1994) has developed the *Methodology for Aquatic Ecological Risk Assessment* which embraces established methodologies developed by the Federal agencies, national laboratories, and private institutions, and contains new, original procedures. The guidance is intended to assist members of the regulated and regulatory communities who need to estimate the effects of toxic chemicals on aquatic communities from new point or nonpoint sources of chemicals, improved wastewater treatment, discharge changes from an existing wastewater treatment facility, and hazardous waste site cleanup or remediation.

USGS

The U.S. Geological Survey (USGS) offers numerous publications on topics relevant to ecological risk assessment (e.g., background water chemistry).

1.7 Federal Facility Agreement

Although there may be subtle differences between a Federal Facility Agreement (FFA) and an IAG, these terms are used interchangeably under CERCLA Section 120 which addresses both NPL and non-NPL sites. This section focuses on the need for early planning and negotiation of an FFA among the USACE customer (a Federal agency), EPA, and the state agency (as appropriate). To accomplish this objective, the HTRW project team member (i.e., the risk assessor) and others should work cooperatively to develop statements/languages or addenda to the FFA early in the HTRW project cycle to define a flexible framework or process for risk management

decision-making and to facilitate a site closeout protective of human health and the environment.

Executive Order 12580 delegates DoD to conduct response action under Section 104 of CERCLA (as amended by SARA) to address releases on DoD facilities or originating from the facilities. The order requires that the response action be conducted in accordance with Section 120 of CERCLA. According to CERCLA Section 120(e)(1), DoD is directed to enter into an IAG with EPA for remedial action within 180 days of EPA's review of the RI/FS. The *Federal Facilities Hazardous Waste Compliance Manual* (EPA 1990c) states, "At a minimum, the IAG must include a review of cleanup alternatives considered and the remedy selected, a schedule for cleanup accomplishment, and arrangements for operation and maintenance" (EPA 1990e).

To address noncompliance issues at a Federal facility (e.g., a DoD installation), EPA may issue a complaint known as Notice of Noncompliance (NON). After such an issuance, EPA and the Federal facility enter into negotiation for a Federal Facility Compliance Agreement (FFCA) which resolves compliance violations and stipulates agreed-upon remedy, compliance schedule, and reporting and recordkeeping requirements. The target date for concluding such an agreement is within 120 days from the date of NON issuance (EPA 1990c). Since RCRA corrective actions are generally required at the time of RCRA Part B permitting or permit renewal, the Federal facility may be issued a RCRA Section 3008(h) corrective action order rather than a NON.

In recent years, model language has been developed to facilitate agreement among the Federal agency, EPA, and the state agency (if applicable) to identify milestones, schedule, requirements, and dispute resolution procedures pertaining to investigation and cleanup at CERCLA and RCRA sites. In the Federal Facility Compliance Agreement (FFCA) of 1992, Federal agencies are no longer afforded with "sovereign immunity" from compliance with state and Federal environmental laws. In the opinion of the Department of Justice (DOJ), however, executive branch agencies may not sue each other nor may one issue an administrative order to another without providing a prior opportunity to contest the order within the executive branch. "Executive branch disputes of a legal nature are properly resolved by the President or his or her delegate..." (EPA 1990a). In view of the above, and for the purpose of this manual, the risk assessor should provide assistance to the USACE's project manager (PM), USACE's technical manager (TM), risk manager, and the USACE customer so that an FFA or IAG can be

successfully negotiated to provide a framework for risk management decision-making and to initiate actions to protect human health and the environment where these actions are needed. The risk assessor and the HTRW project team may consider the following areas for assistance to be provided to the USACE customer concerning the FFA negotiation: these areas have been identified in the DoD-EPA Model IAG Language (EPA 1989d):

1.7.1 Basis for Interim Remedial Action (IRA) Alternatives

For purposes of this guidance, IRA may be interpreted as interim corrective measure under RCRA or removal action under CERCLA. One purpose of the FFA is to identify IRA alternatives which are appropriate at the site prior to the implementation of final remedial action(s). To identify such alternatives, the exposure area (study area or the area of ecological concern), the exposure pathways which contribute to the principal threat at the site, and the receptors/resources must also be identified. For the purpose of the FFA, a statement may be entered which indicates the basis for identifying IRA alternatives. This statement should address the following:

- The approach for conducting a screening risk analysis of the exposure units (EUs) (EPA 1991c), SWMUs, or the AOCs.
- The evaluation method for the risk assessment/analysis results (qualitative or quantitative).
- Risk management decision-making considerations (Chapter 9) for identifying and/or selecting the IRA alternatives.

1.7.2 Requirements for RI/RFI and FS/CMS

Another purpose of the FFA is to provide a framework for investigating, assessing the impact, and evaluating remedial options to protect public health and the environment. Such a framework, consistent with the NCP and the RI/FS guidance (EPA 1988a), may be modified and formally incorporated in the FFA to meet the site-specific and project requirements. Statements or languages or addenda to the FFA may be prepared by the risk assessor and the project team to serve as a basis for determining the extent of data collection, data evaluation, assessment of baseline risk, and evaluation of remedial alternatives. The HTRW data quality design process (USACE 1995b) and associated DQOs should be identified as the framework for determining data needs, data use, and data quality. The point of departure for no-further action and/or

monitoring only based on acceptable risk should be identified in the FFA (EPA 1991d). The statement should indicate the phased approach recommended by this manual and other inputs from the expert ecologist, risk assessor(s), or advisory panels (e.g., BTAG/ETAG; Restoration Advisory Boards/Technical Review Committees [RABs/TRCs]), including criteria used for assessment of uncertainties.

1.7.3 Expedited Cleanup Process

Both DoD and EPA are in agreement that early action or accelerated cleanup may be needed to stabilize the site and to facilitate implementation of the final remedies. However, the basis for such action is not well defined, except that the actions are intended to control contaminant migration, to reduce exposure, and to accelerate response. In addition to time-critical and emergency response actions where safety and acute hazards are involved, the risk assessor and the project team can provide valuable input to the USACE customer and risk manager for such expedited actions. This can be rather quickly accomplished by comparing the measured media concentrations with available human health and ecological risk-based protective criteria. This may be useful for relatively straightforward sites, such as drum removal, product removal, and containment. For response actions at a complex site, a baseline ERA may be more appropriate, however, and expedited cleanup would not be done. All decision criteria for eliciting response actions to protect environmental components should be well thought out, reasonable, and consistent with current EPA guidance.

1.7.4 Units Excluded from the Agreement

RCRA and CERCLA integration issues should be addressed in the FFA in unambiguous terms. This is particularly true for sites of which the state agency is also an interested party or natural resource trustee in the agreement. Some state agencies have their own risk assessment policies and guidances, and risk management decision-making criteria which may vary substantially from those of EPA (EPA's ERA procedures under RCRA and CERCLA are judged to be substantially equivalent at this time). The risk assessor should review state policies, guidance, and requirements, and identify any critical risk assessment/risk management issues for the PM, TM, and the customer for resolution. These issues should be addressed and resolved in the FFA negotiations. If not successful, separate FFAs may be needed to address RCRA and CERCLA units within the facility. The USACE and customer's legal counsels should be contacted for briefing on these issues early in the process.